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Attorney's Docket No.: 17118-059US2/ 2838BUS

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gevas et al.  
Serial No. : 10/829,137  
Filed : April 21, 2004

Art Unit : 1631  
Examiner : Michael L. Borin  
Cust. No. : 20985  
Conf. No. : 6164

Title : PREVENTION AND TREATMENT OF HYPERGASTRINEMIA

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement (3 pages), Form PTO-1449 (5 pages), cited non U.S. patent documents, copies of two foreign actions, a check in the amount of \$180.00, and a return postcard for filing in connection with the above-identified application.



The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie Seidman  
Reg. No. 33,779

Attorney's Docket No.: 17118-059US2 / 2838BUS

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## CERTIFICATE OF MAILING BY "EXPRESS MAIL"

"Express Mail" Mailing Label Number EV 740123727 US

Date of Deposit October 25, 2006

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Seidman



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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, a check for the filing fee of \$180.00 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (5 pages) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Form PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

10/27/2006 WABDELRI 00000055 10829137

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Stephanie Seidman

Provided herewith is a copy of a European Examination Report, issued January 14, 2004, in connection with corresponding European Patent Application No. 99924258.9 (Attorney Docket No. 17118-059EP1/ 2838EP), which is a national stage filing of International Patent Application No. PCT/US99/10751. The instant application is a continuation of U.S. Application Serial No. 09/700,329, which is a National Stage Entry of PCT/US99/10751. Hence, this application and European Patent Application No. 99924258.9 claim priority ultimately to the same parent application. In the Examination Report, Examiner cites five documents: D1 (W09728821); D2 (US5607676); D3 (Watson *et al.*, "Gastrimmune raises antibodies that neutralize amidated and glycine-extended gastrin-17 and inhibit the growth of colon cancer" *Cancer Res.* 56:880-885 (1996)); D4 (McCloy *et al.*, "Pathophysiological effects of long-term acid suppression in man" *Dig. Dis. and Sciences* 40(2):96S-120S [Supplement]) and D5 (Sumii *et al.*, "Regulation of antral peptides by administration of omeprazole to healthy men" *Am. J. Gastroenterol.* 89(11):2033-2037 (1994)). Documents D1-D5 have already been made of record in the instant application in an Information Disclosure Statement, supplied with Forms PTO-1449, filed July 2, 2004.

Provided herewith is a copy of an International Preliminary Examination Report (IPER), issued September 7, 2000, in connection with corresponding International Patent Application No. PCT/US99/10751 (Attorney Docket No. 17118-059WO1/ 2838PC). The instant application is a continuation of U.S. Application Serial No. 09/700,329, which is a National Stage Entry of PCT/US99/10751. In the IPER, Examiner cites seven documents: 1) Watson *et al.*, "Anti-gastrin antibodies raised by gastrimmune inhibit growth of the human colorectal tumor AP5" *Int. J. Cancer*, 61(2):233-240 (1995); 2) Watson *et al.*, "Gastrimmune raises antibodies that neutralize amidated and glycine-extended gastrin-17 and inhibit the growth of colon cancer" *Cancer Res.* 56:880-885 (1996); 3) US5023077; 4) US 5468494; 5) US 5622702; 6) US 5607676 and 7) US 5609870. These documents have already been made of record in the instant application in an Information Disclosure Statement, supplied with Forms PTO-1449, filed July 2, 2004.

Applicant also makes known to the Examiner the following U.S. and international applications, which are commonly owned and/or have one or more inventors in common:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Docket No.</u>
10/762,226	01/20/04	17118-056002/ 2835B
10/235,236	09/04/02	17118-057002/ 2836B
10/323,692	12/19/02	17118-057003/ 2836C

Applicant : Gevas *et al.*  
Serial No. : 10/829,137  
Filed : April 21, 2004

Attorney's Docket No.: 17118-059US2/ 2838BUS  
Supplemental Information Disclosure Statement

10/098,690	03/15/02	17118-058002/ 2837B
10/829,137	04/21/04	17118-059US2/ 2838BUS
11/252,904	10/18/05	17118-060US3/ 2839CUS
10/192,257	07/09/02	17118-063001/ 2842
10/813,336	03/29/04	17118-064001/ 2843
11/360,378	02/22/06	n/a
PCT/US2005/10532	03/29/05	17118-064WO2/ 2843BPC
PCT/IB2006/001572	06/13/06	17118-068WO1/ 2847PC

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents or information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97 (g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56 (b) exists.

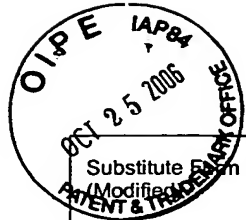
Applicant respectfully requests that the Examiner review the foregoing documents and make them of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie Seidman  
Reg. No. 38,779

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<b>Substitute Disclosure Form PTO-1449</b> (Modified 10/2004) <b>U.S. Department of Commerce</b> <b>Patent and Trademark Office</b>	<b>Attorney's Docket No.</b> 17118-059US2/ 2838BUS	<b>Application No.</b> 10/829,137
	<b>Applicant</b> Gevas et al.	
	<b>Filing Date</b> April 21, 2004	<b>Group Art Unit</b> 1631

**Information Disclosure Statement  
by Applicant**  
(Use several sheets if necessary)

(37 CFR §1.98(b))

**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2002/0058040	05/16/02	Grimes et al.	424	185.1	12/22/00
	AB	2002/0095028	7/18/2002	Grimes et al.	530	412	03/15/02
	AC	2003/0021786	1/30/2003	Gevas et al.	424	146.1	07/09/02
	AD	2003/0086941	5/8/2003	Michaeli et al.	424	185.1	09/04/02
	AE	2003/0091574	5/15/2003	Gevas et al.	424	155.1	03/22/02
	AF	2004/0001842	1/1/2004	Michaeli et al.	424	185.1	12/19/02
	AG	2005/0025770	2/3/2005	Gevas et al.	424	155.1	01/20/04
	AH	2005/0069966	3/31/2005	Grimes et al.	435	7.92	03/29/04
	AI	2006/0020119	1/26/2006	Grimes et al.	530	388.24	03/29/05
	AJ	2006/0039911	2/23/2006	Gevas et al.	424	145.1	10/18/05
	AK	2006/0140962	6/29/2006	Gevas et al.	424	155.1	02/22/06
	AL	4713366	12/15/87	Stevens,	514	13	12/04/85
	AM	4997950	03/91	Murphy et al	548	304.1	04/20/89
	AN	5643735	07/01/97	Yokoi et al.	435	7.9	03/29/95
	AO	5688506	11/18/97	Grimes et al.	424	184.1	01/27/94
	AP	5843446	12/01/98	Ladd et al.	424	184.1	06/07/95
	AQ	6169173	01/02/01	Wank	536	23.5	03/10/93
	AR	6191290	02/20/01	Safavy	549	510	02/23/00
	AS	6303123	10/16/01	Grimes et al.	424	184.1	06/07/95
	AT	6359114	3/19/2002	Grimes et al.	530	344	06/07/95
	AU	6548066	4/15/2003	Michaeli et al.	424	185.1	05/12/98
	AV	6861510	3/1/2005	Gevas et al.	530	388.1	06/06/95

**Foreign Patent Documents or Published Foreign Patent Applications**

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AW	90/08774	08/09/90	PCT				
	AX	95/13297	05/18/95	PCT				

<b>Examiner Signature</b>	<b>Date Considered</b>
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)  <b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17118-059US2/ 2838BUS	Application No. 10/829,137
	Applicant Gevas et al.		
	Filing Date April 21, 2004	Group Art Unit 1631	

### Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AY	99/59612	11/25/99	PCT				
	AZ	99/59631	11/25/99	PCT				
	BA	01/77685	10/18/01	PCT				
	BB	06/032980	03/30/06	PCT				

### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	BC	Abrahm et al., "Development and evaluation of a high affinity species and region specific monoclonal antibody to human gastrin," Gastroenterology, 86(5(2)):1012, (1984).
	BD	Apton Biopharma BIO2005 Presentation, June 19-22, Philadelphia, PA (2005).
	BE	Ardill et al., "Autoantibodies to gastrin in patients with pernicious anaemia- a novel antibody," QJM:monthly journal of the Association of Physicians, 91:739-742, (1988).
	BF	Ausubel, ed., "Current Protocols in Molecular Biology," John Wiley & Sons, New York, pp 11.15.1-11.15.4. (1990).
	BG	Blackmore et al. "Autocrine growth stimulation of human renal Wilms' tumour G401 cells by a gastrin-like peptide," International Journal of Cancer, 57:385-391, (1994).
	BH	Boon, Thierry, "Toward a Genetic Analysis of Tumor Rejection Antigens," Advanced Cancer Research, 58:177-210, (1992).
	BI	Buchan et al., "Regulatory peptides in Barrett's esophagus," Journal of Pathology, 146(3):227-234, (1985).
	BJ	Caplin et al., "Serum gastrin levels and identification of CCK-B-gastrin receptor following partial hepatectomy for liver tumours in man," Gastroenterology, 110(4 suppl.) A1162, (1996).
	BK	Caplin et al., "Expression and processing of gastrin in hepatocellular carcinoma, fibromellar carcinoma and cholangiocarcinoma," Journal of Hepatology, 30(3):519-526, (1999).
	BL	Caplin et al., "Demonstration of new sites of expression of the CCK-B/gastrin receptor in pancreatic acinar AR42J cells using immunoelectron microscopy," Regulatory Peptides, 84(1-3):81-89, (1999).
	BM	Caplin et al., "Effect of gastrin and anti-gastrin antibodies on proliferation of hepatocyte cell lines," Digestive Diseases and Sciences, 46(7):1356-1366, (2001).
	BN	Ciccotosto et al., "Expression, processing, and secretion of gastrin in patients with colorectal carcinoma," Gastroenterology, 109(4):1142-1153, (1995).
	BO	Clerc et al., "Differential Expression of the CCK-A and CCK-B/Gastrin Receptor Genes in Human Cancers of the Esophagus, Stomach, and Colon," International Journal of Cancer, 72:931-936, (1997).
	BP	Ezzell, C., "Cancer 'Vaccines': An Idea Whose Time as Come?," Journal of NIH Research, 7:46-49, (1995).
	BQ	"Gastrin 17 vaccine--Apton: Anti-gastrin 17 immunogen, G17DT", Biodrugs, 17(3):223-225, (2003).
	BR	Gupta et al., "Adjuvants for human vaccines - current status, problems and future prospects," Vaccine, 13(14):1263-1276, (1995).

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(37 CFR §1.98(b))				Filing Date April 21, 2004		Group Art Unit 1631
<b>Other Documents (include Author, Title, Date, and Place of Publication)</b>						
Examiner Initial	Desig. ID	Document				
	BS	Gura, T., "Systems for Identifying New Drugs Are Often Faulty," Science, 278(5340):1041-1042, (1997).				
	BT	Harris et al., "An antiapoptotic role for gastrin and the gastrin/CCK-2 receptor in Barrett's esophagus," Cancer Research, 64(6):1915-1919, (2004).				
	BU	Helander et al., "Immunohistochemical localization of gastrin/CCK-B receptors in the dog and guinea-pig stomach," Acta Physiologica Scandinavica, 159(4):313-320, (1997).				
	BV	Hellmich et al., "Human colorectal cancers express a constitutively active cholecystokinin-B/gastrin receptor that stimulates cell growth," Journal of Biological Chemistry, 275(41):32122-32128, (2000).				
	BW	Herbert et al. (Eds.) "The Dictionary of Immunology," 3rd Ed. Academic Press, London, p. 41, (1995).				
	BX	Herget et al., "Cholecystokinin stimulates Ca <sup>2+</sup> mobilization and clonal growth in small cell lung cancer through CCKA and CCKB/gastrin receptors," Annals of the New York Academy of Sciences, 713:283-297, (1994).				
	BY	Hoosein et al., "Evidence for Autocrine Growth Stimulation of Cultured Colon Tumor Cells by a Gastrin/Cholecystokinin-like Peptide," Experimental Cell Research, 186(1):15-21, (1990).				
	BZ	Jain, R.K., "Barriers to drug delivery in solid tumors," Scientific American, 171(1):58-65, (1994).				
	CA	Kelley et al., "Antitumor activity of a monoclonal antibody directed against gastrin-releasing peptide in patients with small cell lung cancer," Chest, 112:256-261, (1997).				
	CB	Kothary et al., "Identification of gastrin molecular variants in gastrinoma syndrome," Regulatory Peptides, 17:71-84, (1987).				
	CC	Kovacs et al., "Gastrin partially mediates insulin-induced acid secretion in dogs," Peptides, 17(4):583-587, (1996).				
	CD	McWilliams et al., "Antibodies raised against the extracellular tail of the CCKB/gastrin receptor inhibit gastrin-stimulated signaling," Regulatory Peptides, 99(2-3):157-161, (2001).				
	CE	MSNBC News Services, "Mixed results on new cancer drug", November 9, 2000.				
	CF	Moody et al., "GRP receptors are present in non small cell lung cancer cells," Journal of Cellular Biochemistry Supplement, 24:247-256, (1996).				
	CG	Mulholland et al., "Elevated Gastric Acid Secretion in Patients with Barrett's Metaplastic Epithelium" Digestive Diseases and Sciences, 34(9):1329-1334, (1989).				
	CH	Ohning et al., "Gastrin mediates the gastric mucosal proliferative response to feeding," American Journal of Physiology, 271(3(1)):G470-G476, (1996).				
	CI	Osband et al., "Problems in the investigational study and clinical use of cancer immunotherapy," Immunology Today, 11:193-195, (1990).				
	CJ	Rahier et al., "Biosynthesis of Gastrin. Localization of the precursor and peptide products using electron microscopic-immunogold methods," Gastroenterology, 92:1146-1152, (1987).				
	CK	Rehfeld et al., "Residue-specific immunochemical sequence prediction" Journal of Immunological Methods, 171:139-142, (1994).				
	CL	Rehfeld, J.F., "Gastrin and Colorectal Cancer: A Never-Ending Dispute," Gastroenterology, 108(4):1307-1310, (1995).				
	CM	Seva et al., "Growth-promoting effects of glycine-extended progastrin", Science, 265:410-412, (1994).				
Examiner Signature				Date Considered		
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**Other Documents (include Author, Title, Date, and Place of Publication)**

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	CN	Smith, A.M. and S.A. Watson, "Review article: gastrin and colorectal cancer," Alimentary Pharmacology & Therapeutics, 14:1231-1247, (2000).
	CO	Smith et al., "Gastrin and gastrin receptor activation: an early event in the adenoma-carcinoma sequence," Gut, 47(6):820-824, (2000).
	CP	Smith et al., "Gastrin may have an autocrine/paracrine role in Barrett's oesophagus and oesophageal adenocarcinoma," British Journal of Surgery, 84:706-707, (1997).
	CQ	Smith et al., "Gastric carcinoid expresses the gastrin autocrine pathway" British Journal of Surgery, 85:1285-1289, (1998).
	CR	Smith et al., "Phase I/II study of G17-DT, an anti-gastrin immunogen, in advanced colorectal cancer," Clinical Cancer Research, 6(12):4719-4724, (2000).
	CS	Spitler, L.E., "Cancer Vaccines: The Interferon Analogy," Cancer Biotherapy, 10:1-3, (1995).
	CT	Tarasova et al., "Anti-peptide antibodies specific for the gastrin-cholecystokinin-B receptor," Letters in Peptide Science, 1:221-228, (1995).
	CU	Watson et al., "Gastrin: growth enhancing effects on human gastric and colonic tumour cells," British Journal of Cancer, 59:554-558, (1998).
	CV	Watson et al., "Inhibitory effects of the gastrin receptor antagonist (L-365,260) on gastrointestinal tumor cells," Cancer, 68:1255-1260, (1991).
	CW	Watson et al., "Gastrin Receptors in Gastrointestinal Tumors", Medical Intelligence Unit, R.G. Landes Company, Georgetown, TX. pp1-99, (1993).
	CX	Watson et al., "Hypergastrinemia promotes adenoma progression in the APC <sup>Min/+</sup> Mouse Model of Familial Adenomatous Polyposis," Cancer Research, 61:625-631, (2001).
	CY	Watson et al., "Expression of gastrin-CCKB receptor isoforms in gastrointestinal tumor cells: Relationship to gastrin secretion," Proceedings of the American Association for Cancer Research Annual Meeting, 38(0):116 (Abstract 773), (1997).
	CZ	Watson et al., "Antiserum raised against an epitope of the cholecystokinin B/gastrin receptor inhibits hepatic invasion of a human colon tumor," Cancer Research, 60(20):5902-5907, (2000).
	DA	Watson et al., "Gastrin antagonists and gastrointestinal tumors," Expert Opinion on Investigational Drugs, 4(12):1253-1266, (1995).
	DB	Watson et al., "Antibodies raised by gastrimmune inhibit the spontaneous metastasis of a human colorectal tumour AP5LV," European Journal of Cancer, 35(8):1286-1291, (1999).
	DC	Watson et al., "Antibodies targeting the Amino Terminal portion of the Human CCKB/gastrin receptor inhibit the liver invasion of a human colonic tumour," Research Presentation, Digestive Disease Week, American Gastroenterological Association, (1998).
	DD	Watson et al., "A comparison of an anti-gastrin antibody and cytotoxic drugs in the therapy of human gastric ascites in SCID mice," International Journal of Cancer, 81(2):248-254, (1999).
	DE	Watson, S.A. and A.D. Gilliam, "A new weapon in the therapeutic armoury for gastrointestinal malignancy," Expert Opinion on Biological Theory, 1(2):309-317, (2001).
	DF	Watson et al., "Inhibition of gastrin-stimulated growth of gastrointestinal tumour cells by octreotide and the gastrin/cholecystokinin receptor antagonists, proglumide and lorglumide," European Journal of Cancer, 28A(8-9):1462-1467, (1992).
	DG	Watson et al., "Intracellular gastrin in human gastrointestinal tumor cells," Journal of the National Cancer Institute, 83:866-872, (1991).

Examiner Signature	Date Considered
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				Filing Date April 21, 2004		Group Art Unit 1631	
<b>Other Documents (include Author, Title, Date, and Place of Publication)</b>							
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	DH	Watson et al., "The in vitro growth response of primary human colorectal and gastric cancer cells to gastrin," International Journal of Cancer, 43:692-696, (1989).					
	DI	Watson et al., "Therapeutic effect of the gastrin receptor antagonist, CR2093 on gastrointestinal tumour cell growth," British Journal of Cancer, 65(6):879-883, (1992).					
	DJ	Weiner, L.M., "An Overview of Monoclonal Antibody Therapy of Cancer," Seminars in Oncology, 26(4)(Supp. 12):41-50, (1999).					
	DK	Zeng et al., "Localization of PACAP receptors on rat fundic ECL and D cells," Gastroenterology, 110(4 Suppl.):A1136, (Abstract), (1996).					

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